Implants
trauma

HOL
Hallux Osteotomy Locking Plate
All ITS plates are preformed anatomically as a matter of principle. If adjustment of the plate to the shape of the bone is required, this is possible by carefully bending gently in one direction once. Particular care is required when bending in the region of a plate hole, as deformation of the plate may lead to a failure of the locking mechanism. The plate must not be buckled or bent several times. This is particularly important in the case of titanium implants, to prevent material fatigue and subsequent failure. The method of bending is the conscious responsibility of the operating doctor; I.T.S. GmbH can accept no liability whatsoever for this.
1. Introduction

P. 5 Preface
P. 6 Screw
P. 6 Properties
P. 7 Intruments
P. 8 Indications & Contraindications

2. Surgical Technique

P. 10 Pre-operative patient preparation
P. 10 Assembling of the insertion / removal instrumentation
P. 11 Access
P. 11 Osteotomy
P. 12 Determination of plate size
P. 12 Plate insertion
P. 12 Optional fixation with guide wire
P. 13 Drilling
P. 13 Identification of screw length
P. 14 Placement of the screw
P. 14 Wound closure
P. 15 Postoperative treatment
P. 15 Explantation
P. 15 Case study

3. Information

P. 17 Locking / Dotize®
P. 18 Order list
P. 20 Reconditioning Manual
P. 22 Notes
Introduction
Preface

The Hallux Osteotomy Locking Plate from ITS. is an intramedullary self-locking plate for distal metatarsal osteotomies.

When the screw is inserted the 2 flanks are splayed out, and the implant acquires a firm intramedullary hold.

The special feature of this implant is the ability to choose your preferred osteotomy technique, the simple and brief surgical procedure, the stable implant position and weightbearing.
Screw

37303-XX  Cancellous Stabilization Screw, D=3.0mm, RH
61183-100  Spiral Drill, D=1.8mm, L=100mm, AO Connector
54095-100  Torque-Shank, T9x100

Properties

Properties of the material:
- Plate material: Titanium
- Material of screws: TiAl6V4 ELI
- Easier removal of the implant after the fracture has healed
- Improved fatigue strength of the implant
- Reduced risk of cold welding
- Reduced risk of inflammation and allergy

Properties of the implant:
- Multi-directional locking
- Intramedullary locking
- Minimization of soft tissue irritation due to the anatomical plate design
- Free selection of the most common osteotomy techniques
- Primary stability
- Simple surgical procedure
- Brief operation time
- 3 different plate sizes: 8, 9, 10mm
Instruments

AO Handle:
- AO Connector
- Cannulated

Depth Gauge:
- One-hand design
- Ability to measure through the insertion / removal instrumentation

Insertion / removal instrumentation:
- AO Connector
- Plateau for simple insertion & removal
- Ability to insert the screw through the insertion / removal instrumentation

Implant Depth Gauge:
- 3-star implant depth gauge to measure the correct plate size
○ Indications, Contraindications

Indications:

- Intramedullary self-locking plate for distal metatarsal osteotomies
- For Hallux Valgus up to a corrective angle of 25°

Contraindications:

- Existing bone or soft tissue infections at the surgical site
- Common situations that do not allow osteosynthesis
- With advanced osteoporosis
- Skin and soft-tissue problems which prevent a tension-free closure of the skin
- Obesity
- Lack of patient compliance
Surgical Technique

2.
○ Pre-operative patient preparation
  • Position the patient supine on a radiolucent table
  • Leg freely mobile

○ Assembling of the insertion / removal instrumentation
Access

Medial access

- Access is on the medial side of the first metatarsal bone subcapitally (osteotomy height) to distal of the base of the joint of the first metatarsal bone.
- Dependent on the hospital, execution of a lateral capsulotomy and tenotomy.
- Horizontal capsular incision and removal of the thickened capsular lobe from the extosis (potential fusiform capsular resection).

Osteotomy

- Leveling of the plate bed or removal of the pseudoextosis with a finely oscillating saw. Not to exceed the level of the shaft diaphysis. The smoothened surface acts as a bed for the plate head.
- Selection of the desired osteotomy technique (Chevron, Austin, Hohmann, ...)
- Execution of the osteotomy while preserving the soft tissue using an atraumatic cut which generates as little heat as possible.

Caution: In order to guarantee the greatest possible stability, the implant must rest flat on the small head of the first metatarsal bone.
- Determination of plate size
  - The size of the plate is determined with the assistance of the implant depth gauge (59028).
  - The implant depth gauge has 3 ends of different sizes which correspond to the 3 sizes of the Hallux Osteotomy Plate.
  - Beginning with smallest, the 3 ends are inserted intramedullary.

- Plate insertion / optional fixation with guide wire
  - In accordance with the measured size, the plate is inserted freely or with the aid of the insertion/removal instrumentation (62702 & 62702-5) in an intramedullary position - or with light hammer blows on the plateau.
  - Additionally, the Hallux Osteotomy Plate can be temporarily fixed with a guide wire, D=1.2mm, L=100mm, TR, w. thrd. (35124-100).
  - Subsequent control under fluoroscopy.

  - The location of the small head of the shaft can be adjusted where necessary with the insertion axis and angle.
Drilling

Drilling is performed with the spiral drill, D=1.8mm, L=100mm, AO Connector (61183-100) through the eye of the plate head at a right angle where possible (+/- 15° Locking).

**Caution:** Heed the correct position and bone contact of the small head of the first metatarsal bone.

Drill through the fixation screw (62702-5) when using the insertion / removal instrumentation (62702).

**Caution:** To avoid disruption of soft tissue, nerves and/or blood vessels use an oscillating drill.

Identification of screw length

- When measuring with the depth gauge (59027) through the fixation screw at the insertion / removal instrumentation, read off the required screw length on the rear edge of the sliding handle.

- When measuring directly on the plate, read off the required screw length on the front edge of the sliding handle.
**Placement of the screw**

- In accordance with the measured length, a cancellous stabilization screw, D=3.0mm, RH (37303-XX) is now inserted with the Torque-Shank, T9x100 (54095-100).
- The screw can be inserted by the insertion/removal instrumentation (62702) or freely after removal of the fixation screw.
- Final control under fluoroscopy.

**Caution:** When inserting the screw ensure that the screw head is flush with the plate.

**Wound closure**

- Suture the capsule with absorbable sutures
- Drainage is usually not necessary
- Suture the skin
- Apply the appropriate dressing
• **Postoperative treatment**
  - Elevation and preventative edema measures on the day of the operation
  - Mobilization with forefoot relief shoe
  - Free weightbearing according to symptoms and stipulations of the operating surgeon

• **Explantation**
  - Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs.
  - Implant removal is performed after radiographic verification of the healed bone, vice versa of implantation
  - Skin incision following the old scar
  - Remove the screw with the Torque-Shank, T9x100 (54095-100)
  - Remove the plate simply by pulling (e.g. with a hook) or with the insertion / removal instrumentation - optional light hammer blows on the plateau
  - The problem of cold welding was resolved by using a special surface treatment (for further information see page 17)

• **Case study**

  **Case 1:**

Pre-, intra- and postoperative x-rays of Hallux Valgus
Information
**Locking**

**Locking works because:**

- Screw material (TiAlV) is slightly harder than plate material (Titanium Grade 2)
- Screw head **forms** thread into the plate (no cutting)

**Benefits:**

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

**Dotize®**

**Chemical process - anodization in a strong alkaline solution***

<table>
<thead>
<tr>
<th><strong>Type III anodization</strong></th>
<th><strong>Dotize Type II anodization</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Layer thickness 60-200nm</td>
<td>- Layer thickness 2000-10 000nm</td>
</tr>
<tr>
<td>- Different <strong>colors</strong></td>
<td>+ Film becomes an interstitial part of the titanium</td>
</tr>
<tr>
<td>- Implant surface remains sensitive to:</td>
<td>- No visible cosmetic effect</td>
</tr>
<tr>
<td>Chipping</td>
<td></td>
</tr>
<tr>
<td>Peeling</td>
<td></td>
</tr>
<tr>
<td>Discoloration</td>
<td></td>
</tr>
</tbody>
</table>

**Anodization Type II leads to following benefits***

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

---

* *White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander*
### Order list

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallux Osteotomy Plate, 8mm</td>
<td>21015-08</td>
</tr>
<tr>
<td>Hallux Osteotomy Plate, 9mm</td>
<td>21015-09</td>
</tr>
<tr>
<td>Hallux Osteotomy Plate, 10mm</td>
<td>21015-10</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=10mm, RH</td>
<td>37303-10</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=12mm, RH</td>
<td>37303-12</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=14mm, RH</td>
<td>37303-14</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=16mm, RH</td>
<td>37303-16</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=18mm, RH</td>
<td>37303-18</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=20mm, RH</td>
<td>37303-20</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=22mm, RH</td>
<td>37303-22</td>
</tr>
<tr>
<td>Cancellous Stabilization Screw, D=3.0mm, L=24mm, RH</td>
<td>37303-24</td>
</tr>
<tr>
<td>AO Handle</td>
<td>53013</td>
</tr>
<tr>
<td>Torque-Shank, T9x100</td>
<td>54095-100</td>
</tr>
<tr>
<td>Depth Gauge, Hallux Osteotomy Plate</td>
<td>59027</td>
</tr>
<tr>
<td>Implant Depth Gauge, Hallux Osteotomy Plate</td>
<td>59028</td>
</tr>
<tr>
<td>Spiral Drill, D=1.8mm, L=100mm, AO Connector</td>
<td>61183-100</td>
</tr>
<tr>
<td>Insertion / Removal Instrumentation, Hallux Osteotomy Plate</td>
<td>62702</td>
</tr>
<tr>
<td>Fixation Screw, Hallux Osteotomy Plate</td>
<td>62702-5</td>
</tr>
<tr>
<td>Guide Wire, D=1.2mm, L=100mm</td>
<td>35124-100</td>
</tr>
<tr>
<td>Sterilization Tray, Hallux Osteotomy Plate</td>
<td>50233</td>
</tr>
</tbody>
</table>
Tray
Reconditioning Manual

The information below should help you in reconditioning medical devices.

**IMPORTANT INDICATIONS FOR DOCTORS & OPERATING THEATRE PERSONNEL**

This instruction leaflet refers to all supplied non-sterile implants and all reusable instruments from I.T.S. GmbH. Detailed information for the identification of the product (such as system classification, cat. no.) can be found in the product identification code and/or on the packaging label. Make sure that you are familiar with the possible application, combinability and correct handling of the product. Please note that product systems can undergo modifications which can affect the combinability of the implant with other implants or instruments. Detailed user information can be found in the respective surgical instructions.

**Intended Use of the Implant**

The implant temporarily stabilises bone segments until bony consolidation has taken place. After this, the implant has no more use and can be removed.

**Indications and Contra-Indications of the Implant**

Indications and contra-indications are determined by current medical practice.

**Side Effects of the Implant**

Up to now, no allergic reactions have been identified with titanium implants. Allergic reactions to steel implants cannot be ruled out.

**Warnings and Preventive Measures**

- Pay attention to the instructions on the packaging.
- Implants are only to be used once.
- Always treat implants carefully to avoid surface damage or geometric alterations.
- Any alterations to the design of implants from I.T.S. GmbH are prohibited.
- All the following described steps for cleaning and sterilization are made easier when contaminants (e.g. blood) are not allowed to dry beforehand.
- Staff who come into contact with contaminated or potentially contaminated medical products should follow the generally recognised preventive measures. Due care is to be taken when handling medical products with sharp points or edges.
- Appropriate protective measures must be taken to ensure safe handling when dealing with contaminated or potentially contaminated medical products.
- In countries with stricter safety requirements regarding recycling medical products, these safety requirements apply and are to be adhered to.
- Any supplied non-sterile medical products must be thoroughly prepared according to these instructions before use.
- Have each instrument that can be dismantled subjected to manual cleaning purposes. The use of these materials can lead to damage of surfaces and coatings. Instead, soft brushes made of nylon should be used.
- Steam (damp heat) is the recommended sterilization method of medical products.
- Manual cleaning/disinfection

A manual cleaning and disinfection procedure, even when using an ultrasound bath, should generally be avoided and should only be used if an automatic process is not available, due to very low levels of efficacy. In addition, the manual procedure can be used to support automatic reconditioning, particularly in the case of heavily soiled instruments.

**Restrictions**

- Unless otherwise stated, repeated preparation of re-usable instruments of I.T.S. GmbH has minimal effects on them when following the procedures mentioned below.
- The end of the product service life is usually determined by wear and damage caused by use.
- Instruments containing aluminium or anodised aluminium can be damaged by alkaline (pH value > 7) cleaning agents and solutions.

**INSTRUCTIONS FOR RECYCLING REUSABLE INSTRUMENTS**

Preparation at the location of use

- Remove surface dirt using a disposable cloth or paper towel. Rinse out the hollow parts with A. dest. Saline solution (NaCl) only may be used if reconditioning is carried out immediately afterwards – risk of corrosion!

Storage and Transport

- No special requirements.
- It is recommended that medical products are reconditioned as soon as possible after their previous use.

---

**Cleaning/Drying**

**Cleaning preparation**

Each instrument that can be dismantled should be taken apart before cleaning.

**Automatic cleaning/disinfection**

Only a washer-disinfector (WD) that conforms to standards (in accordance with EN ISO 15883) and that is regularly maintained and inspected should be used for automatic cleaning and disinfection in accordance with the manufacturer’s information. Recommended equipment: Appropriate loading trolleys to accommodate all instruments (e.g. instrument trolleys with MIC bar; MIC trolleys); commercially available cleaning agent authorised for use with medical products (pH value 9-11) e.g. Neodisher® Mediclean forte by Dr. Weigers. I.T.S. GmbH recommends the following validated steps for automatic cleaning and thermal disinfection. The basic device should be a Miele PG 633E machine. Validation is carried out in accordance with EN ISO 15883 and guideline no. 3 of the Austrian Association for Sterile Services (OGSV).

---

**Reconditioning Manual**

**Cleaning**

**Cleaning**

Pre-rinsing 1

Pre-rinsing 2

Cleaning

Rinsing

Thermal disinfection

Drying

**Phase** | **Water quality** | **Temperature [°C]** | **Time [min]** | **Dosage**
--- | --- | --- | --- | ---
Pre-rinsing 1 | SW | cold | 2 | -
Pre-rinsing 2 | SW | cold | 5 | -
Cleaning* | PW | 55 | 10* | 6 - 45
Rinsing | SW | 50 | 3 | -
Thermal disinfection | PW | 90 | 5 | -
Drying | - | 10 | 15 | -

**SW:** Softened water; **PW:** Purified water; **DT:** Dosage temperature

**Cleaning agent:** Neodisher® Mediclean forte

**Step 1**

Jointed instruments are to be opened so that water can flow out of cannulae and blind holes. Place cannulated instruments onto or connect them to appropriate rinsing nozzles (use a rinsing adapter where necessary).

**Step 2**

Start the relevant cycle.

Adhere to the guidelines of the WD manufacturer.

**Step 3**

After removing the instruments from the disinfector, check the cannulae, blind holes, etc. for visible dirt. If required, repeat cycle or clean by hand.

---

**Manual cleaning/disinfection**

A manual cleaning and disinfection procedure, even when using an ultrasound bath, should generally be avoided and should only be used if an automatic process is not available, due to very low levels of efficacy. In addition, the manual procedure can be used to support automatic reconditioning, particularly in the case of heavily soiled instruments.

Recommended equipment: Commercially available cleaning agent authorised for medical products (pH value 9-11) or combined cleaning agent and disinfectant (e.g. Sekusept® Aktiv 2% by ECOLAB), nylon brushes with soft bristles; running water.

---

**Accessories**

Genie automatic positioning of the instruments using non-free soft cloths, paper towels or soft plastic brushes.

**Soaking the instruments**

Fully submerge and soak the instruments in a suitable cleaning agent and disinfectant solution. Manufacturer’s information, e.g. concerning concentration, temperature and exposure time should be followed when using all agents.

**Cleaning agent/disinfectant**

Use of a cleaning agent/disinfectant from the VAH list. I.T.S. GmbH recommends Sekusept® Aktiv 2% by ECOLAB. When using powdered products, it must first be checked that the powder has dissolved completely in the water before the instruments are added. In addition, adhere to the manufacturer’s information regarding material tolerances. If applicable: the cleaning agent must be suitable for ultrasound cleaning (non-foaming).

Do not use highly alkaline or acidic additives. Recommended pH range 4.5 - 8.5. Prepare freshly every day.

**Ultrasound treatment**

Treatment in an ultrasound bath is carried out for 5 minutes in the abovementioned cleaning agent/disinfectant. The instrument set is then left in the solution for 5 minutes.

**Rinsing/drying the instruments**

Remove the instruments from the solution and rinse thoroughly with running tap water until there are no visible traces of blood or other contaminants in the rinsing water. Particular attention should be paid to lumens, openings and other areas that are not easily accessible. Rubber and flexible plastics require longer rinsing times and any dirt that remains on the instruments may have to be removed manually (no metal brushes, no abrasive cleaners). Thorough final rinsing using purified water. Dry the instruments immediately (e.g. using a lint-free disposable cloth or pressurised air gun).
Manual disinfection
If a cleaning agent without a disinfectant effect is used, separate disinfection must be carried out after manual cleaning. (Order: Decontamination for staff protection, cleaning, disinfection).

Equipment: Commercially available disinfectant authorised for use with medical products from the VAH list. Manufacturer’s information, e.g. concerning concentration, temperature and exposure time should be followed. The steps described in the table above also apply.

Drying
See table above.

Checking, Maintenance and Inspection
• Each instrument or implant is to be inspected carefully to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/disinfection cycle should be repeated.
• Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilisable surgical instruments.
• The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
• In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

Packaging
The delivery packaging is purely for transport purposes and is not suitable for sterilisation. The hospital is responsible for in-house procedures regarding assembly, inspection and packaging of instruments. Packaging is carried out in accordance with the general standard packaging guidelines of relevant standards and guidelines of specialist organisations using sterile barrier systems that conform with standards.

Sterilization
• All instruments and implants should be laid out in such a way that the steam can reach all the surfaces of the medical devices.
• Each instrument that can be dismantled should be taken apart for sterilisation.
• Carry out sterilisation of the products using the fractionated pre-vacuum procedure, in accordance with EN 285 (or EN 13060) and EN ISO 17665. I.T.S. GmbH recommends the following validated methods for sterilising instruments:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Duration of sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>(345°C, 77°F)</td>
<td>5 minutes (8 minutes*)</td>
</tr>
</tbody>
</table>

* Parameters for sterilisation with steam recommended by the World Health Organization (WHO) for recycling instruments if contamination with Creutzfeldt-Jakob Disease (CJD) pathogens is suspected.

Disposal
The valid guidelines of the hospital operator apply for disposal.

Responsibility of the Hospital for Instruments lent by I.T.S. GmbH
• Surgical instruments generally have a long service life. But their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments which no longer work correctly, whether due to wear, misuse or improper care, have to be disposed of.
• Medical products which are returned to I.T.S. GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to I.T.S. GmbH must be accompanied by a confirmation of the decontamination they were subjected to.

Important information
• The above-mentioned instructions have been validated by the manufacturer of medical devices for reconditioning a medical device, the re-use of which is deemed to be suitable. It is the responsibility of the reconditioner to ensure that reconditioning actually carried out using the equipment, materials and staff available in the preparation facility achieves the desired results. For this, validation and routine inspections of the process are necessary. Likewise, any deviation from the instructions provided by the reconditioner should be evaluated for its efficiency and possible negative consequences.
• Should you have questions or problems, please contact us at the address above.

Symbols

Patient information
Implantation has consequences for the discomfort, mobility and general life circumstances of the patient. For this reason, the patient should be given instructions about appropriate behaviour to adopt after implantation, and it should be explained to him or her the necessity and the importance of reporting negative changes in the area of the implant as well as any falls and accidents which may appear not to have damaged the implant or the site of the operation.

---

Manual disinfection
If a cleaning agent without a disinfectant effect is used, separate disinfection must be carried out after manual cleaning. (Order: Decontamination for staff protection, cleaning, disinfection).

Equipment: Commercially available disinfectant authorised for use with medical products from the VAH list. Manufacturer’s information, e.g. concerning concentration, temperature and exposure time should be followed. The steps described in the table above also apply.

Drying
See table above.

Checking, Maintenance and Inspection
• Each instrument or implant is to be inspected carefully to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/disinfection cycle should be repeated.
• Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilisable surgical instruments.
• The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
• In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

Packaging
The delivery packaging is purely for transport purposes and is not suitable for sterilisation. The hospital is responsible for in-house procedures regarding assembly, inspection and packaging of instruments. Packaging is carried out in accordance with the general standard packaging guidelines of relevant standards and guidelines of specialist organisations using sterile barrier systems that conform with standards.

Sterilization
• All instruments and implants should be laid out in such a way that the steam can reach all the surfaces of the medical devices.
• Each instrument that can be dismantled should be taken apart for sterilisation.
• Carry out sterilisation of the products using the fractionated pre-vacuum procedure, in accordance with EN 285 (or EN 13060) and EN ISO 17665. I.T.S. GmbH recommends the following validated methods for sterilising instruments:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Duration of sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>(345°C, 77°F)</td>
<td>5 minutes (8 minutes*)</td>
</tr>
</tbody>
</table>

* Parameters for sterilisation with steam recommended by the World Health Organization (WHO) for recycling instruments if contamination with Creutzfeldt-Jakob Disease (CJD) pathogens is suspected.

Disposal
The valid guidelines of the hospital operator apply for disposal.

Responsibility of the Hospital for Instruments lent by I.T.S. GmbH
• Surgical instruments generally have a long service life. But their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments which no longer work correctly, whether due to wear, misuse or improper care, have to be disposed of.
• Medical products which are returned to I.T.S. GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to I.T.S. GmbH must be accompanied by a confirmation of the decontamination they were subjected to.

Important information
• The above-mentioned instructions have been validated by the manufacturer of medical devices for reconditioning a medical device, the re-use of which is deemed to be suitable. It is the responsibility of the reconditioner to ensure that reconditioning actually carried out using the equipment, materials and staff available in the preparation facility achieves the desired results. For this, validation and routine inspections of the process are necessary. Likewise, any deviation from the instructions provided by the reconditioner should be evaluated for its efficiency and possible negative consequences.
• Should you have questions or problems, please contact us at the address above.