TightLine Development

IMPORTANT INFORMATION

Exodus Disposable Kit Instructions for Use

Issue date: September 2023

STERILE

TightLine Development, LLC
One Glenlake Parkway, Suite 650
Atlanta, GA 30328
info@tightlinedevelopment.com
www.tightlinedevelopment.com
Patents: www.tightlinedevelopment.com/patents

Description

The Disposable Kit is used in conjunction with the Exodus Strikeplate Handle to aid in hip and knee implant removal.

The instruments are provided STERILE and should not be reused. The instruments are comprised of stainless steel.

Indications for Use

The *Hip Revision Kit: Femoral Stem Removal* includes three osteotomes whose geometry uniquely enables access to the area around a well-fixed stem. It is intended for use during surgical procedures associated with implant revision or removal processes.

General Safety Notes

1. Product shall only be used and maintained by qualified and trained healthcare practitioner.
2. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.
3. It is the duty of the user to ensure that resources and materials are available to capable personnel; and that hospital protocols and policies are followed.
4. Users should always wear appropriate personal protective equipment when using and maintaining the product.

Warnings

1. Product is provided STERILE and are single patient use devices. Do not reuse or re-sterilize. The instruments should be checked for proper function prior to use.
2. All packaging materials must be removed prior to use.
3. Mixing of components from different suppliers is not recommended for reasons of compatibility, mechanics and design. TightLine Development disclaims any liability in case of incompatible components from different sources being used.
4. Care should be taken not to cut through surgical gloves when handling and to consider the risk of infection if a cut appears.

Inspection

1. Instrument packaging should be inspected for breach of the sterile barrier before it is used. Any breach of the sterile barrier should result in disposal of the instruments.
2. Visually inspect instruments for damage due to shipping or transport. If damage that may compromise the function of the instrument is noted, do not use the instrument and notify the appropriate personnel.
3. Check that the devices assemble readily with mating components.

Storage and Handling

1. Storage zones should be away from areas of humidity to avoid excessive corrosion. This recommendation is equally valid for the transport and packaging.

Document #: 00-510-944-01-Rev03

2. Store in a dry, clean and dust free environment at temperatures between 5°C to 40°C (41°F to 104°F).
3. Once used, the instruments should be discarded in the appropriate manner for single-use instruments in accordance with hospital policy (e.g. sharps container). Instruments should NOT be resterilized.

Important Statement

It is strictly prohibited to carry out any modification whatsoever. Only TightLine Development has the competence to carry out such work. If this recommendation is not followed, TightLine Development disclaims any liability for any subsequent consequences.

Symbols

REF — Catalogue number *(ISO 15223-1, Clause 5.1.6)*	Date of manufacture *(ISO 15223-1, Clause 5.1.3)*	Caution *(ISO 15223-1, Clause 5.4.4)*
LOT — Lot number *(ISO 15223-1, Clause 5.1.5)*	STERILE — Sterile *(ISO 15223-1 (Clause 5.2.1))*	Consult instruction for use *(ISO 15223-1, Clause 5.4.3)*
Keep dry *(ISO 15223-1, Clause 5.3.4)*	SN — Serial number *(ISO 15223-1, Clause 5.1.7)*	Recyclable *(non-standard)*
Manufacturer *(ISO 15223-1, Clause 5.1.1)*	Do not use if package is damaged	Rx only — Prescription only *(21 CFR 801.15(c)(1)(i)F)*
Do Not Reuse *(ISO 15223-1 (Clause 5.4.2))*	Use-by Date *(ISO 15223-1 (Clause 5.1.4))*	STERILE R — Sterilization by Irradiation *(ISO 15223-1 (Clause 5.2.4))*
Consult instruction for use *(non-standard)*		