

AtriClip® Selection Guide
 Instructions for Use
 MD

FIGURE 1

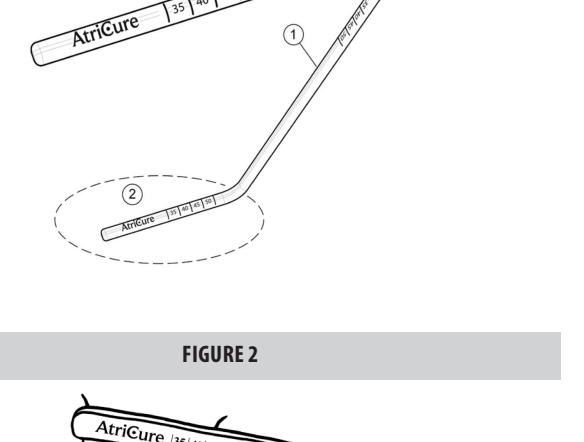


FIGURE 2



INSTRUCTIONS FOR USE

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AtriClip® Selection Guide

INTENDED PURPOSE

The AtriClip Selection Guide is used to aid in the selection of the appropriate AtriClip for exclusion of the left atrial appendage.

INDICATION FOR USE

The AtriClip Selection Guide (G) is used to aid in the selection of the appropriate AtriClip for exclusion of the left atrial appendage with the AtriClip AA Exclusion System.

CONTRAINDICATIONS

Intended medical doctor who performs cardiac and/or thoracic procedures.

INTENDED PATIENT POPULATION

Intended for those with thromboembolic risk who are anatomically eligible for left atrial appendage exclusion.

INTENDED CLINICAL BENEFIT

Exclusion of the atrial appendage from the left atrium to reduce the risk of stroke.

DEVICE

An intended medical device which works in conjunction with the AtriClip AA Exclusion System. The AtriClip AA Exclusion System is composed of the AtriClip AA Exclusion Device (G), the AtriClip Applier, and the Guide.

ENVIRONMENTAL SPECIFICATIONS

Storage: Temperature: -20°C to 20°C or 60°C/140°F

Temperature: -20°C to 60°C/140°F

Relative Humidity: 10% to 85%

Atmospheric Pressure: N/A

Atmospheric Druck: N/A

PACKAGE CONTENTS

1. One (1) Guide

The Guide is supplied STERILE and NON-PYROGENIC in an unopened, undamaged package. For single use only. Do not re-use.

2. Sterile technique

Read all instructions for the Guide before use as the device only is intended to be used by trained medical personnel. Intended use of this device may lead to device damage if not used correctly.

3. Do not use the Guide if the device is not sterile.

Do not use the Guide if it is intended for SINGLE use only.

Re-sterilization of the Guide is not recommended.

The Guide is supplied STERILE and is intended for SINGLE use only.

INSTRUCTIONS FOR USE

1. Using sterile technique, remove the Guide from its packaging.

2. Align the Guide with the JAA (See Figure 2).

NOTE: Removal of the Guide should be at the base of the appendage.

3. Evaluate the AtriClip and select the appropriate Clip size.

CAUTION: The Guide is to be used only to assist with selecting the appropriate Clip.

WARNING

Do not apply excessive force when using the Guide. Using excessive force may cause tissue damage.

Read all instructions for the Guide before use as the device only is intended to be used by trained medical personnel. Intended use of this device may lead to device damage if not used correctly.

Do not use the Guide if the device is not sterile.

Do not use the Guide if it is intended for SINGLE use only.

Re-sterilization of the Guide is not recommended.

The Guide is supplied STERILE and is intended for SINGLE use only.

WARNING

If the sterile package is damaged and/or the sterile barrier is breached, discard the device and do not reuse.

Replace with a new device.

CAUTION: Do not drop the device as this may cause damage to the device. If the device is dropped, do not use.

Replace with a new device.

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If the sterile package is damaged and/or the sterile barrier is breached, do not use the device and do not reuse.

CAUTION: Do not drop the device as this may result in an adverse patient reaction.

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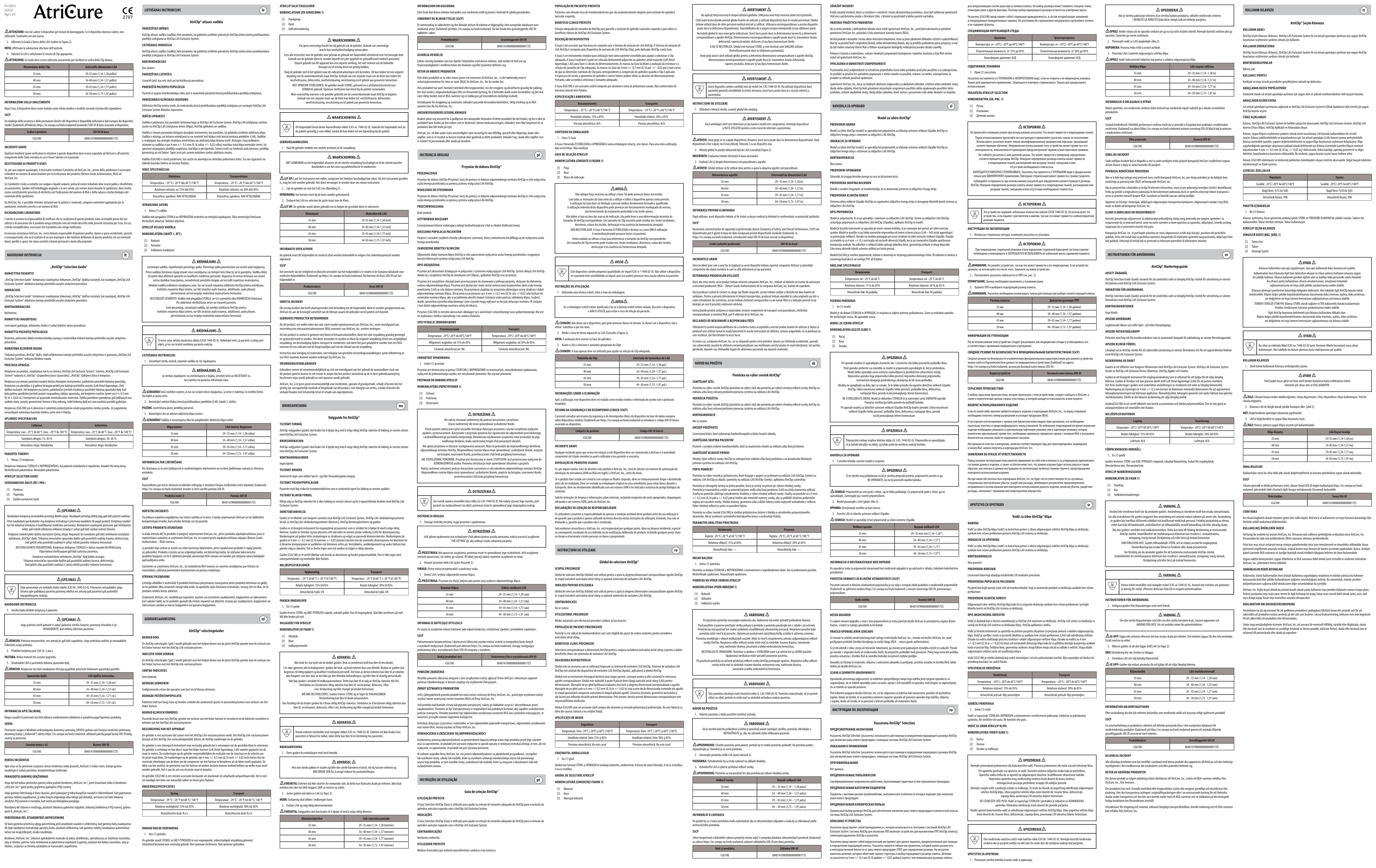
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