Rapid Arches

Manufacturer:

Smart Denture Conversions, LLC
1800 N. Salem St.
Suite 104
Apex NC, 27523
855-550-0707
www.SmartDentureConversions.com

Training:

The following descriptions are insufficient to allow immediate use of the Smart Denture Conversions' system. Knowledge of implant-prosthetic treatment and instruction in the handling of the Smart Denture Conversions' system provided by an operator with the relevant experience are necessary. It is strongly recommended that new and experienced users of Smart Denture Conversions' products complete special training before using a new product for the first time. Smart Denture Conversions offers a variety of training options. Please go the www.SmartDentureConversions.com for more information.

Product Description:

Rapid Arches are pre-manufactured acrylic impression trays that resemble a natural dentition and can be modified to serve as a template for a fixed or removable prosthesis. Rapid Arches sets come in 9 different configurations to accommodate small, medium, and large arches in square, tapered, or round arch forms for both upper and lower dentures. The table below summarizes the items:

Denture Size	Description	Compatible Trilor Bar	Material	# of Uses
STU	Small Tapered Upper	ST	PMMA	Single-Use
STL	Small Tapered Lower	ST		
SRU	Small Round Upper	R1		
SRL	Small Round Lower	R1		
SSU	Small Square Upper	R1		
SSL	Small Square Lower	R1		
MTU	Medium Tapered Upper	R2		
MTL	Medium Tapered Lower	ST		
MRU	Medium Round Upper	R2		
MRL	Medium Round Lower	R2		
MSU	Medium Square Upper	SS		
MSL	Medium Square Lower	R1		
LTU	Large Tapered Upper	LR		
LTL	Large Tapered Lower	R2		
LRU	Large Round Upper	LR		
LRL	Large Round Lower	R2		
LSU	Large Square Upper	LR		
LSL	Large Square Lower	SS		

Intended Use/Indications for Use:

Rapid Arches are intended to be used as trays that allow for impression material or acrylic to customize the fit to the patient's anatomy.

Rapid Arches are indicated for use with Smart Denture Conversions' Trilor Reinforcement Bars and other prosthetic products. Rapid Arches are intended for single use. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartDentureConversions.com.

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Contraindications:

It is contraindicated to using Smart Denture Conversions' Rapid Arches in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who show signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

Warning:

- Components are to be used by dental health care professionals and are to be used in patients subject to dental implant treatment.
- If the indication or the nature of use is not clear, do not use until all points have been clarified.
- Do not use if package is damaged.
- Always inspect components before use. Do not use damaged, deformed, corroded, or discolored components.
- Ensure products are secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
- Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications: Aspiration or swallowing of a component, follow-up treatment, incorrect impression resulting in incompatible restorations.
- As the clinical outcome of dental treatment is influenced by multiple variables, even if the product is used according to the instructions for use the residual risks described below can. anaphylaxis (severe allergic reaction); aspiration or swallowing of components; pain; local infection; inflammation; local irritation; loss of product function; follow-up treatment.
- Smart Denture Conversions is not liable for damage resulting from use outside the intended use of the product.

Cautions/Precautions:

The following precautions are required before or during treatment:

- Do not use Smart Denture Conversion components after the expiration date on packaging (if applicable).
- All products intended for single use must not be reused. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components.
- Before every procedure make sure that all required components, instruments, and auxiliary equipment are complete, in operating order and available in the required quantity.
- If, due to unfavorable anatomical conditions, instruments do not fit or cannot be used for other reasons, the course of treatment planned with them must not be continued and alternatives must be sought.
- Always wear suitable personal protective equipment for your own safety.
- Position the patient such that the danger of aspiration of components is minimized.
- All components used in the patient's mouth must be secured to prevent aspiration and swallowing.

Magnetic Resonance Imaging (MRI) Safety Information:

All Smart Denture Conversion LLC products which remain in the patient's body have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Smart Denture Conversion LLC products in the MR environment is unknown. Scanning a patient who has such a product may result in patient injury.

Disinfection:

Rapid Arches should be disinfected prior to use on a patient to ensure safety and prevent the risk of infection. An intermediate disinfectant, such as Chlorhexidine gluconate (0.12%), should be used. Follow the manufacturer's instructions for the correct application, ensuring adequate contact time to achieve effective disinfection. Ensure that the device is clean and free from any contaminants before applying the disinfectant to maximize efficacy.

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Note: This device should not be steam sterilized, as exposure to high temperatures and moisture may cause the part to deform and compromise its functionality.

Storage, Handling and Transportation:

The devices must be stored in a dry place in their original packaging at room temperature and protected from direct sunlight. Improper storage may compromise essential material and design characteristics, leading to device failure.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy. Separation, recycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable. If there is no current legislation, pack them in a perforating waste/sharps disposal container and dispose of them in hospital waste.

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Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Catalog Number	Basic UDI-DI Number
Rapid Arch Large Round Lower 1PK, Shade BL2	RA-LTU1PK-BL2	+D990RALRL1PKBL20
Rapid Arch Medium Round Lower 1PK, Shade BL2	RA-MTU1PK-BL2	+D990RAMRL1PKBL20
Rapid Arch Small Round Lower 1PK, Shade BL2	RA-STU1PK-BL2	+D990RASRL1PKBL20
Rapid Arch Large Square Lower 1PK, Shade BL2	RA-LTL1PK-BL2	+D990RALSL1PKBL20
Rapid Arch Medium Square Lower 1PK, Shade BL2	RA-MTL1PK-BL2	+D990RAMSL1PKBL20
Rapid Arch Small Square Lower 1PK, Shade BL2	RA-STL1PK-BL2	+D990RASSL1PKBL20
Rapid Arch Large Tapered Lower 1PK, Shade BL2	RA-LRU1PK-BL2	+D990RALTL1PKBL20
Rapid Arch Medium Tapered Lower 1PK, Shade BL2	RA-MRU1PK-BL2	+D990RAMTL1PKBL20
Rapid Arch Small Tapered Lower 1PK, Shade BL2	RA-SRU1PK-BL2	+D990RASTL1PKBL20
Rapid Arch Large Round Upper 1PK, Shade BL2	RA-LRL1PK-BL2	+D990RALRL1PKBL20
Rapid Arch Medium Round Upper 1PK, Shade BL2	RA-MRL1PK-BL2	+D990RAMRL1PKBL20
Rapid Arch Small Round Upper 1PK, Shade BL2	RA-SRL1PK-BL2	+D990RASRL1PKBL20
Rapid Arch Large Square Upper 1PK, Shade BL2	RA-LSU1PK-BL2	+D990RALSL1PKBL20
Rapid Arch Medium Square Upper 1PK, Shade BL2	RA-MSU1PK-BL2	+D990RAMSL1PKBL20
Rapid Arch Small Square Upper 1PK, Shade BL2	RA-SSU1PK-BL2	+D990RASSL1PKBL20
Rapid Arch Large Tapered Upper 1PK, Shade BL2	RA-LSL1PK-BL2	+D990RALTL1PKBL20
Rapid Arch Medium Tapered Upper 1PK, Shade BL2	RA-MSL1PK-BL2	+D990RAMTL1PKBL20
Rapid Arch Small Tapered Upper 1PK, Shade BL2	RA-SSL1PK-BL2	+D990RASTL1PKBL20
Rapid Arch Complete Library, Shade BL2	RA-CL-BL2	+D990RACLBL20
Rapid Arch Large Round Lower 1PK, Shade A1	RA-LRL1PK-A1	+D990RALRL1PKA10
Rapid Arch Medium Round Lower 1PK, Shade A1	RA-MRL1PK-A1	+D990RAMRL1PKA10
Rapid Arch Small Round Lower 1PK, Shade A1	RA-SRL1PK-A1	+D990RASRL1PKA10
Rapid Arch Large Square Lower 1PK, Shade A1	RA-LSL1PK-A1	+D990RALSL1PKA10
Rapid Arch Medium Square Lower 1PK, Shade A1	RA-MSL1PK-A1	+D990RAMSL1PKA10
Rapid Arch Small Square Lower 1PK, Shade A1	RA-SSL1PK-A1	+D990RASSL1PKA10
Rapid Arch Large Tapered Lower 1PK, Shade A1	RA-LTL1PK-A1	+D990RALTL1PKA10
Rapid Arch Medium Tapered Lower 1PK, Shade A1	RA-MTL1PK-A1	+D990RAMTL1PKA10
Rapid Arch Small Tapered Lower 1PK, Shade A1	RA-STL1PK-A1	+D990RASTL1PKA10
Rapid Arch Large Round Upper 1PK, Shade A1	RA-LRU1PK-A1	+D990RALRU1PKA10
Rapid Arch Medium Round Upper 1PK, Shade A1	RA-MRU1PK-A1	+D990RAMRU1PKA10
Rapid Arch Small Round Upper 1PK, Shade A1	RA-SRU1PK-A1	+D990RASRU1PKA10
Rapid Arch Large Square Upper 1PK, Shade A1	RA-LSU1PK-A1	+D990RALSU1PKA10
Rapid Arch Medium Square Upper 1PK, Shade A1	RA-MSU1PK-A1	+D990RAMSU1PKA10
Rapid Arch Small Square Upper 1PK, Shade A1	RA-SSU1PK-A1	+D990RASSU1PKA10
Rapid Arch Large Tapered Upper 1PK, Shade A1	RA-LTU1PK-A1	+D990RALTU1PKA10
Rapid Arch Medium Tapered Upper 1PK, Shade A1	RA-MTU1PK-A1	+D990RAMTU1PKA10
Rapid Arch Small Tapered Upper 1PK, Shade A1	RA-STU1PK-A1	+D990RASTU1PKA10
Rapid Arch Large Round Lower 1PK, Shade A2	RA-LRL1PK-A2	+D990RALRL1PKA20
Rapid Arch Medium Round Lower 1PK, Shade A2	RA-MRL1PK-A2	+D990RAMRL1PKA20
Rapid Arch Small Round Lower 1PK, Shade A2	RA-SRL1PK-A2	+D990RASRL1PKA20
Rapid Arch Large Square Lower 1PK, Shade A2	RA-LSL1PK-A2	+D990RALSL1PKA20
Rapid Arch Medium Square Lower 1PK, Shade A2	RA-MSL1PK-A2	+D990RAMSL1PKA20
Rapid Arch Small Square Lower 1PK, Shade A2	RA-SSL1PK-A2	+D990RASSL1PKA20
Rapid Arch Large Tapered Lower 1PK, Shade A2	RA-LTL1PK-A2	+D990RALTL1PKA20
Rapid Arch Medium Tapered Lower 1PK, Shade A2	RA-MTL1PK-A2	+D990RAMTL1PKA20
Rapid Arch Small Tapered Lower 1PK, Shade A2	RA-STL1PK-A2	+D990RASTL1PKA20

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Rapid Arch Large Round Upper 1PK, Shade A2	RA-LRU1PK-A2	+D990RALRU1PKA20
Rapid Arch Medium Round Upper 1PK, Shade A2	RA-MRU1PK-A2	+D990RAMRU1PKA20
Rapid Arch Small Round Upper 1PK, Shade A2	RA-SRU1PK-A2	+D990RASRU1PKA20
Rapid Arch Large Square Upper 1PK, Shade A2	RA-LSU1PK-A2	+D990RALSU1PKA20
Rapid Arch Medium Square Upper 1PK, Shade A2	RA-MSU1PK-A2	+D990RAMSU1PKA20
Rapid Arch Small Square Upper 1PK, Shade A2	RA-SSU1PK-A2	+D990RASSU1PKA20
Rapid Arch Large Tapered Upper 1PK, Shade A2	RA-LTU1PK-A2	+D990RALTU1PKA20
Rapid Arch Medium Tapered Upper 1PK, Shade A2	RA-MTU1PK-A2	+D990RAMTU1PKA20
Rapid Arch Small Tapered Upper 1PK, Shade A2	RA-STU1PK-A2	+D990RASTU1PKA20
Rapid Arch Large Round Lower 1PK, Shade B1	RA-LRL1PK-B1	+D990RALRL1PKB10
Rapid Arch Medium Round Lower 1PK, Shade B1	RA-MRL1PK-B1	+D990RAMRL1PKB10
Rapid Arch Small Round Lower 1PK, Shade B1	RA-SRL1PK-B1	+D990RASRL1PKB10
Rapid Arch Large Square Lower 1PK, Shade B1	RA-LSL1PK-B1	+D990RALSL1PKB10
Rapid Arch Medium Square Lower 1PK, Shade B1	RA-MSL1PK-B1	+D990RAMSL1PKB10
Rapid Arch Small Square Lower 1PK, Shade B1	RA-SSL1PK-B1	+D990RASSL1PKB10
Rapid Arch Large Tapered Lower 1PK, Shade B1	RA-LTL1PK-B1	+D990RALTL1PKB10
Rapid Arch Medium Tapered Lower 1PK, Shade B1	RA-MTL1PK-B1	+D990RAMTL1PKB10
Rapid Arch Small Tapered Lower 1PK, Shade B1	RA-STL1PK-B1	+D990RASTL1PKB10
Rapid Arch Large Round Upper 1PK, Shade B1	RA-LRU1PK-B1	+D990RALRU1PKB10
Rapid Arch Medium Round Upper 1PK, Shade B1	RA-MRU1PK-B1	+D990RAMRU1PKB10
Rapid Arch Small Round Upper 1PK, Shade B1	RA-SRU1PK-B1	+D990RASRU1PKB10
Rapid Arch Large Square Upper 1PK, Shade B1	RA-LSU1PK-B1	+D990RALSU1PKB10
Rapid Arch Medium Square Upper 1PK, Shade B1	RA-MSU1PK-B1	+D990RAMSU1PKB10
Rapid Arch Small Square Upper 1PK, Shade B1	RA-SSU1PK-B1	+D990RASSU1PKB10
Rapid Arch Large Tapered Upper 1PK, Shade B1	RA-LTU1PK-B1	+D990RALTU1PKB10
Rapid Arch Medium Tapered Upper 1PK, Shade B1	RA-MTU1PK-B1	+D990RAMTU1PKB10
Rapid Arch Small Tapered Upper 1PK, Shade B1	RA-STU1PK-B1	+D990RASTU1PKB10
Rapid Arch Complete Library, Shade A1	RA-CL-A1	+D990RACLA10
Rapid Arch Complete Library, Shade A2	RA-CL-A2	+D990RACLA20
Rapid Arch Complete Library, Shade B1	RA-CL-B1	+D990RACLB10

Validity:

Upon publication of these instructions for use, all previous versions are superseded.

Availability:

Some items of Smart Denture Conversions are not available in all countries.

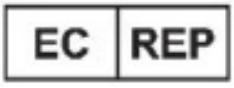
Warranty:

Please visit www.SmartDentureConversions.com for the most up to date warranty information.

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Symbols Glossary:

The following Symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

	Manufacturer		Date of Manufacture
	Use By Date		Serial Number
	Batch Code		Catalog Number
	Unique Device Identifier		Medical Device
	CE Mark		UK Representative
	United Kingdom Conformity Assessment Mark		United Kingdom Conformity Assessment Mark with Approved Body Number
	European Representative		Non-Sterile
	Comes Sterilized		Comes Sterilized using Aseptic Processing
	Comes Sterilized using Ethylene Oxide Processing		Comes Sterilized using Irradiation Processing
	Comes Sterilized using Dry Heat Processing		Do Not Resterilize
	Do Not Reuse		Consult Instructions for Use
	Keep Dry		Keep Away from Sunlight
RX Only	For Prescription Use Only		Caution, Consult Accompanying Documents
	Do Not Use if Packaging is Damaged		