

HYGENIC[®] Waxes

Instructions for Use

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Rx ONLY

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

 **COLTENE**

Baseplate Wax

Intended Use/ Indications for Use:

Baseplate Waxes are intended for use in the fabrication of temporary record bases and occlusal rims and for the arrangement of artificial denture teeth. Baseplate Waxes are indicated for use in denture try-in procedures.

Baseplate Waxes are also intended for bite registration to record the relationship of the upper & lower teeth and are indicated for use in dentulous patients.

Baseplate Wax is intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s)

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Baseplate Waxes aid in the fabrication of dental prostheses.

Characteristics:

- Extra Tough wax is tough, pliable and sufficiently tacky to hold teeth well. It takes a high polish and boils out clean. The wax is good for try-in procedures.
- Medium Soft No. 3 pink wax is slightly softer than Extra Tough. It takes a high polish which allows an accurate preview of dentures or partial dentures and boils out clean. Medium Soft No. 3 is also excellent for taking accurate bites and quadrant checks.
- Red Wax has the same great features as Medium Soft No. 3 wax, but it is red in color.

Note: Waxes are poor conductors of heat and cold. A full five-pound box of wax with lid removed requires approximately 24 hours to achieve a complete and uniform temperature change throughout, i.e. 55°F (13°C) storage temperature to 75°F (24°C) working temperature at a room temperature of 75°F (24°C). More severe temperature differentials may occur on shipments received during the winter season. To ensure satisfactory pliability of Hygenic sheet waxes, the following minimum working temperature should be reached:

- All Baseplate Waxes 70°F (21°C)

Note: If time does not allow for the wax to be brought up to minimum working temperatures, flaming or other warming procedures may be necessary.

Note: If wax residue is left on the record base from the wax occlusal rim, consult the instructions for use of the record base material for cleaning instructions.

Note: Remove wax residue from artificial denture teeth with clean boiling water.

Instructions

Recommended Step by Step Instructions:

Occlusal Rim Fabrication

1. If necessary, soften the wax sheet in warm water to ensure even heat distribution.
2. Fold or roll the wax sheet across the short end and manipulate to create a horseshoe shape. Adapt the wax to the record base.
3. The wax should be sealed to the baseplate with a heated dental wax carver.
4. A heated dental wax carver may be used to modify the occlusal rim to the desired dimension and contour.
5. Cool to room temperature.

CAUTION! Do not expose wax to high temperatures. Store formed wax occlusion rims away from heat sources.

Arranging Teeth

1. When arranging artificial teeth on the wax occlusal rim, a heated dental wax carver should be used to cut and contour the wax.

Bite Registration

WARNING! Inspect wax prior to use. Discard brittle wax. Use of brittle wax intraorally is a choking hazard.

CAUTION! Do not use hot wax for bite registration as minor burns may result.

1. If necessary, soften the wax sheet in warm water to ensure even heat distribution.

2. Fold the sheet to the desired shape for the specific bite registration.
3. Place the wax into the patient's mouth and instruct the patient to close into the desired position.
4. If warmed, allow the wax to cool before removing from the patient's mouth.
5. A heated dental wax carver may be used to remove any excess wax.
6. The wax is now ready for use with the models for articulation.

Parts List

Catalog #	Description	Color
H00803	Extra Tough Wax, 1 lb. (450 g.)	Pink
H00805	Red Wax, 1 lb. (450 g.)	Red
H00806	Medium Soft No. 6 Pink Wax, 1 lb. (450 g.)	Pink
H00809	Extra Tough Wax, 5 lb. (2.25 kg.)	Pink
H00811	Red Wax, 5 lb. (2.25 kg.)	Red
H00812	Medium Soft No. 3 Pink Wax, 5 lb. (2.25 kg.)	Pink

Boxing Wax

Intended Use:

Boxing Wax is intended for boxing impressions.

Boxing Wax is intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Boxing Wax is not intended to be used on a patient, rather Boxing Wax is intended to be used in a laboratory setting by a dental laboratory technician.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Boxing Waxes aid in the fabrication of dental prostheses.

Characteristics:

- Boxing Wax is designed to withstand the extreme heat given off by dental stones during setting.
- Length: 12" (305 mm)
- Width: 1.5" (38 cm)
- Thickness: 1/16" (1.6 mm) regular or,
- Thickness: .04" (1 mm) extra thin

Instructions

Boxing a Full Denture Impression

1. Ensure the impression is dried thoroughly.
2. Beading: Adapt a strip of wax around the impression below its peripheral height to create the land area of the cast. The wax strip can be pressed into place and sealed to the impression with a heated dental carver and additional wax. We recommend the use of Hygenic Square Wax Ropes (H00819 or H00820) for beading.
3. Attach a strip of boxing wax around the beading wax so that an enclosed border is produced around the entire impression.
4. Ensure all open areas or joints are pressed together and sealed with hot wax to prevent plaster or stone from leaking through. A heated dental wax carver may be used to seal the wax or remove excess boxing wax.
5. The plaster or stone can now be poured into the space created by the wax.
6. After the cast has set, the wax can be removed, and the cast is ready for further processing.

Parts List

Catalog #	Description	Color
H00815	Boxing Wax, Regular, 450 g	Red
H00816	Boxing Wax, Extra Fine, 450 g	Red
H00837	Boxing Wax, Regular 2.25 kg	Red
H00838	Boxing Wax, Extra Fine, 2.25 kg	Red

Bite Wafers

Intended Use:

Bite Wafers are intended for bite registration to record the relationship of the upper & lower teeth and are indicated for use in dentulous patients.

Bite Wafers are intended for Single Use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Bite Wafers aid in the fabrication of dental prostheses.

Characteristics:

- The Blue Bite Wafers contain aluminum foil laminated between two layers of wax which stabilizes the wafer preventing bite through and lessens distortion
- Shaped for full arch coverage

Instructions

Bite Registration

WARNING! Inspect wax prior to use. Discard brittle wax. Use of brittle wax intraorally is a choking hazard.

CAUTION! Do not use hot wax for bite registration as minor burns may result.

1. If necessary, soften the wax wafer in warm water to ensure even heat distribution.
2. Place the wax into the patient's mouth and instruct the patient to close into the desired position.
3. If warmed, allow the wax to cool before removing from the patient's mouth.
4. A heated dental wax carver may be used to remove any excess wax.
5. If desired, chill the wax wafer further with cold water.
6. The wax is now ready for use with the models for articulation.

Parts List

Catalog #	Description	Color	Quantity
H00825	Bite-Wafers, Double, 24 pcs	Blue	24 per box
H00839	Bite-Wafers, Yellow, Soft, 50 pcs	Yellow	50 per box
H03365	Bite-Wafers, Green, Hard, 36 pcs	Green	36 per box

Yellow Bite Wax

Intended Use:

Yellow Bite Wax is intended for bite registration to record the relationship of the upper & lower teeth and are indicated for use in dentulous patients.

Yellow Bite Wax is intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Yellow Bite Wax aids in the fabrication of dental prostheses.

Characteristics:

- Easily softened under warm water

Instructions

Bite Registration

WARNING! Inspect wax prior to use. Discard brittle wax. Use of brittle wax intraorally is a choking hazard.

CAUTION! Do not use hot wax for bite registration as minor burns may result.

1. If necessary, soften the wax wafer in warm water to ensure even heat distribution.
2. Place the wax wafer into the patient's mouth and instruct the patient to close into occlusion.
3. If warmed, allow the wax wafer to cool before removing from the patient's mouth.
4. A heated dental wax carver may be used to remove any excess.
5. If desired, chill the wax wafer with cold water.
6. The wax wafer is now ready for use with the models for articulation.

Parts List

Catalog #	Description	Color
H00807	Yellow Bite Wax, 450 g	Yellow
H00813	Yellow Bite Wax, 2.25 kg	Yellow

Occlusal Rims

Intended Use:

Performed Occlusal Rims are intended for use in the fabrication of occlusal rims and for the arrangement of artificial denture teeth. Occlusal Rims are indicated for use in denture try-in procedures.

Occlusal Rims are intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Occlusal Rims aid in the fabrication of dental prostheses.

Characteristics:

- Preformed
- Can be reshaped at room temperature
- Recessed base aids adaptation to the baseplate

Instructions

Occlusal Rim Fabrication

1. Reshape the occlusal rim to the desired contour.
2. Adapt the occlusal rim to the record base.
3. The occlusal rim should be sealed to the baseplate with a heated dental wax carver.
4. A heated dental wax carver may be used to modify the occlusal rim to the desired dimension and contour.
5. Cool to room temperature.

CAUTION! Do not expose wax to high temperatures. Store formed wax occlusion rims away from heat sources.

Parts List

Catalog #	Description	Color
H00822	U-Shaped Occlusal Rim Wax, Standard Package, 100 pcs	Pink
H04030	U-Shaped Occlusal Rim Wax, Lab Package, 21 pcs	Pink

Utility Wax

Intended Use:

Utility Wax is intended for use in the denture impression process to adapt impression trays.

Utility Wax is also intended for use with boxing wax when boxing impressions.

Utility Wax is intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Utility Waxes aid in the fabrication of dental prostheses.

Characteristics:

- 11" (279 mm) long
- Round or Square
- Red or White

Instructions

Adapting Impression Trays

1. Select the desired impression tray and ensure it is thoroughly dried.
2. Cut the wax strip to the desired length. A heated dental wax carver may be used, if necessary.
3. Extend the tray where necessary by lining the periphery of the tray with the strip of wax.
4. Stops can be created in the tray by adding the appropriately sized wax strip at the desired location.
5. A post dam can be created by adding the wax to the end of the tray.

Boxing a Full Denture Impression

1. Adapt a strip of the utility wax around the impression below its peripheral height to create the land area of the cast. We recommend the use of Square Wax Ropes (H00819, H00820).
2. Attach a strip of boxing wax around the beading wax so that an enclosed form is produced around the entire impression. We recommend the use of Hygenic Boxing Wax (H00815, H00816, H00837, or H00838).
3. The plaster or stone can now be poured into the space created by the wax.

Parts List

Catalog #	Description	Color
H00817	Round Wax Strips, Red, 80 pcs	Red
H00818	Round Wax Strips, White, 80 pcs	White
H00819	Square Wax Ropes, Red	Red
H00820	Square Wax Ropes, White	White

Orthodontic Tray Wax

Intended Use:

Orthodontic Tray Wax is intended for use in the impression process to adapt impression trays. The wax can be used to extend the periphery, post dam or create stops.

Orthodontic Tray Wax is intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Orthodontic Tray Wax aids in the impression process.

Characteristics:

- Soft and Tacky
- Easily molded at room temperature, no heating required

Instructions

Adapting Impression Trays

1. Select the desired impression tray and ensure it is thoroughly dried.
2. A heated dental wax carver may be used to cut the wax strip to the desired length.
3. Extend the tray where necessary by lining the periphery of the tray with the strip of wax.
4. Stops can be created in the tray by adding the appropriately sized wax strip at the desired location.
5. A post dam can be created by adding the wax to the end of the tray.

Parts List

Catalog #	Description	Color
H00827	HYGENIC Orthodontic Tray Wax, White, 48 pcs	White

Plastic Wax Sticks

Intended Use:

Plastic Wax Sticks are intended for use in the impression process to adapt impression trays. The wax can be used to expand the peripheral edge, post dam and other areas of the impression tray.

Plastic Wax Sticks intended for single use.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s):

Suitable for all patient groups.

Clinical Benefits:

There are no direct clinical benefits. The Hygenic Plastic Wax Sticks aid in the impression process.

Characteristics:

- Soft and Tacky
- Easily molded at room temperature, no heating required

Instructions

Adapting Impression Trays




1. Select the desired impression tray and ensure it is thoroughly dried.
2. A heated dental wax carver may be used to cut the wax strip to the desired length.
3. Extend the tray where necessary by lining the periphery of the tray with the strip of wax.
4. Stops can be created in the tray by adding the appropriately sized wax strip at the desired location.
5. A post dam can be created by adding the wax to the end of the tray.

Parts List



Catalog #	Description	Color
H00826	Wax Sticks, Scented, 48 pcs	Blue



Hygienic Waxes

Warnings







Warnings	Statement
 WARNING!	Failure to properly follow the directions in this IFU may result in patient injury or compromise the integrity of the procedure. Use the product only in accordance with its intended use, see <i>Intended Use</i> .
 WARNING!	Do not reuse. Wax strips, pieces or sheets are intended to be used only once. Reuse of wax intraorally is a biological hazard and can result in cross contamination. Reuse of laboratory wax can result in loss of performance.
 WARNING!	Wax should be inspected prior to use. Discard brittle wax. Use of brittle wax intraorally is a choking hazard.






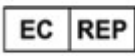
Precautions

Precautions	Statement
 CAUTION	It is recommended to wear appropriate personal protection equipment (PPE) when handling the waxes.
 CAUTION	Do not expose wax to high temperatures. Store formed wax occlusion rims away from heat sources.

Precautions	Statement
 CAUTION	Do not use hot wax for bite registration as minor burns may result.
 CAUTION	Dental waxes have a specified shelf life. Do not use the device after the Use-by Date because the device functionality and performance characteristics may be compromised.

Symbols Glossary

Symbol	Title and Description of Symbol
	Caution/ Warning
 www.coltene.com	Consult electronic instructions for use - Indicates the need for the user to consult the instructions for use
	Medical Device – Indicates the item is a medical device
	Sale Restricted: The purchase of the device is restricted to licensed healthcare practitioners only.
	Use-by Date - Indicates the date after which the medical device is not to be used
	Catalog Number - Indicates the manufacturer's catalogue number so that the medical device can be identified

Symbol	Title and Description of Symbol
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	CE mark
	Importer - Indicates the entity importing the medical device into the locale
	Manufacturer - Indicates the medical device manufacturer
	Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified
	Authorized representative in the European Community - Indicates the authorized representative in the European Community

Note: Dispose of device in accordance with local, regional, national, and/or international regulations. Devices used intraorally should be treated as a biohazard and disposed of properly per local regulations.




Upon request, a hardcopy of the IFU will be supplied free of charge.

For users located in the EU: Any serious incident that has occurred in relation to the use of Hygenic Waxes should be reported to Coltène/Whaledent, Inc. and the competent authority of the member state in which the user and/or patient is established.

Check www.coltene.com for the most up to date Instructions for Use.

Storage

- Store Hygenic Waxes between 60°F - 70°F (16°C - 21°C)
- Keep dry and keep away from heat

Symbol	Title and Description of Symbol
	Keep dry - Indicates a medical device that needs to be protected from moisture
	Keep away from heat - Indicates a medical device that needs protection from heat
	Temperature Limit - Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.

Hygienic Waxes



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